EVERTING STAPLE DEVICES AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

The subject matter of this application is related to the subject matter of commonly assigned U.S. Applications Nos. 60/187,428, filed March 7, 2000 and 60/201,594, filed May 3, 2000, both of which are incorporated herein by reference and priority to which is claimed under 35 U.S.C. § 119(e).

BACKGROUND OF THE INVENTION

1. Field of Invention

The invention relates to devices and methods for anastomosing two or more anatomical structures, such as vascular structures. Embodiments according to the invention are desirable in both minimally invasive and conventional surgical situations. Certain embodiments have particular application to minimally invasive direct coronary artery bypass (MIDCAB) and off-pump (OPCAB) procedures, for example.

2. Description of Related Art

Surgical connections (anastomoses) between two tubular structures of soft tissue (e.g. blood vessels) typically are fashioned with "linkage" devices, such as flexible suture or rigid staples. Such anastomoses involve surgical incisions of the two soft tissue structures, which result in cut edges. These edges ideally are excluded from the inside channel (lumen) of the two joined structures. Ideally, the linkage devices are also excluded from the lumen.

The suture- and staple-type linkage devices of the prior art, however, do not always achieve the above-described ideal; cut tissue edges and the linkage devices themselves sometimes are exposed to the lumen. See Figures 1A-1D, for example, which show unpredictable eversion and exclusion of cut edges 10 (of ends 20, 30 of anatomical structures 40, 50) and suture 60 from lumen 70 when sutures alone are used, as in the prior art.

SUMMARY OF THE INVENTION

In view of these and other disadvantages, a need exists for devices and methods that consistently, predictably and reliably evert the edges of an e.g. circumferential anastomosis between two tubular anatomical structures, e.g. a vascular anastomosis between the left internal mammary artery and the left anterior descending coronary artery. Such devices and methods can be used alone, or in conjunction with a biological adhesive product, suture, or other supplemental products or devices. They can be part of a sutured or stapled anastomosis, i.e. an anastomosis using one or more sutures and/or staples in combination with the devices of the invention.

The ultimate purpose, according to embodiments of the invention, is to substantially ensure inner-layer-to-inner-layer (e.g. intima-to-intima) approximation completely circumferentially at the anastomotic site, with no portion of the cut edges of the tissues or suture or staple exposed to the lumen of the anastomosis. Instead, embodiments of the invention substantially ensure that the cut edges of the tissues, as well as the linkage device, are completely extra-lumenal. With such embodiments, the entire circumference of both structures of the anastomosis is completely everted.

Embodiments of the invention provide a number of advantages. For example, the invention provides a more precise, completely everted anastomosis more predictably than heretofore possible with staples or suture alone. Embodiments of the invention are believed to result in a higher patency rate in vascular anastomoses, by eliminating cut edges of tissue or foreign bodies (e.g. sutures or staples) from the lumen. Such tissue edges or foreign bodies, if left exposed to the lumen, can threaten the patency of the anastomosis by allowing thrombus (clot) formation and/or fibrosis or intimal hyperplasia (scarring), ultimately resulting in stenosis (narrowing) or occlusion. Embodiments of the invention, on the other hand, cause immediate and long-term improvements in patency and therefore quality of life and longevity.

Further, embodiments of the invention allow a smaller number of anastomotic eversion devices to be used, e.g. in conjunction with a biological adhesive or equivalent. Such hybrid procedures allow for a simpler, more expeditious anastomosis, with either conventional or minimally invasive techniques, with or without the aid of cardiopulmonary bypass.

Still further, according to embodiments of the invention, everting platforms on an outer radius of a closed everting staple assure that a penetrating element of the staple is excluded from the lumen, because the penetrating element is on a different, inner radius. Spacing elements according to the invention assure a space between everting platforms of the staple in a closed configuration of the staple, negating any tissue necrosis at the level of intima-to-intima approximation.

Penetrating and spacing elements according to embodiments of the invention may cause tissue damage, but such damage is outside of the anastomosis, i.e. it is at or near the inner radius of the closed staple. Nevertheless, spacing elements and/or penetrating elements according to

such embodiments have small surface area, to minimize tissue necrosis. To effect parallel alignment of the everting platforms, the staple is "scissored" in the closed position thereof. One of the everting platforms is offset accordingly.

By providing two everting platforms on a single piece of wire or other material constituting the staple, according to embodiments of the invention, the need to deliver an opposing everting platform from an opposite side of an anastomosis is eliminated. Other features and advantages according to embodiments of the invention will become apparent from the remainder of this application.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will be described with reference to the figures, in which like reference numerals refer to like elements and in which:

Figures 1A - 1D show one type of prior art anastomosis technique using a suture alone, with unpredictable eversion and exclusion of cut edges and suture from the lumen;

Figure 2 is a panoramic view of an open staple according to an embodiment of the invention, with an everting platform, offset everting platform, two spacing elements and penetrating element as shown;

Figure 3 is a panoramic view of a closed, "scissored" staple with two radii and two axes according to an embodiment of the invention. More specifically, Figure 3 shows an outer radius of the illustrated everting platforms, an inner radius of the spacing and penetrating elements, and side-by-side offset axes of the closed staple;

Figure 4 is a side view of a staple according to an embodiment of the invention, showing the penetrating element, spacing elements, and everting platforms;

Figure 5 is a side view of closed staple enclosing tissue, according to an embodiment of the invention, showing the penetrating element, everting platforms and spacing elements;

Figure 6 is a side view showing the inner radius of the spacing and penetrating elements and the outer radius of the everting platforms;

Figure 7 is an end view of a closed staple enclosing tissue, according to an embodiment of the invention, showing the penetrating element, everting platforms and spacing elements;

Figure 8 is an inside view of a open staple, according to an embodiment of the invention, showing the penetrating element, everting platforms and spacing elements, and the direction of closure of the staple;

Figure 9 is an outside view of an open staple, according to an embodiment of the invention, showing the penetrating element, everting platforms and spacing elements, and the direction of closure of the staple;

Figure 10 is a perspective view of a staple and an eversion platform, according to an embodiment of the invention;

Figure 11 is a side view of an eversion platform with overhanging collar, according to an embodiment of the invention;

Figure 12 is a side, cross-sectional view of a stapled anastomosis in a staple-open, platforms-apart configuration;

Figure 13 is a side, cross-sectional view of a stapled anastomosis in a staple-closed, platforms-apposed configuration;

Figure 14 is a side view showing the inner radius of the staple and the outer radius of the eversion platforms; and

Figure 15 is a panoramic view of an end-to-side anastomosis in a staple-closed configuration.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A first embodiment of surgical staple 100 for creating a completely everted anastomosis is shown in Figures 2-9. Staple body 110 of surgical staple 100 is constructed to bend, e.g. at 120 in Figure 3. At opposite ends of staple body 110, staple 100 includes everting platforms or elements 130, 140 that protrude from staple body 110. Everting platform 130 is centered with respect to longitudinal axis 145 of staple body 110. As illustrated, a central portion 146 of everting platform 130 is connected to the very end of staple body 110. Everting platform 140, on the other hand, is connected to staple body 110 at its end 148, not at a central portion thereof. Thus, as shown in e.g. Figures 8-9, everting platforms 130, 140 are offset with respect to each other, in a transverse direction with respect to axis 145.

Surgical staple 100 also includes first spacing element 150, disposed adjacent staple body 110 at the very end thereof. Specifically, spacing element 150 is adjacent to longitudinal axis 145 thereof and above everting platform 130, as viewed in e.g. Figures 2 and 8. Staple 100 also includes second spacing element 160, disposed along staple body 110 at the opposite end thereof and generally in line with longitudinal axis 145 thereof. Spacing elements 150, 160 are closer to the middle of staple body 100 than are everting platforms 130, 140. Spacing elements 150, 160

can be generally tapered, as shown at e.g. 165 in Figures 2 and 8. Of course, other placements and shapes of spacing elements 150, 160 are contemplated.

Penetrating element 170 is constructed to penetrate the anatomical structures being anastomosed, in a manner to be described, and is disposed at one end of staple body 110. Penetrating element 170 is disposed generally along longitudinal axis 145 of staple body 110 and is generally perpendicular or transverse, or otherwise angled, to it.

Staple 100 is constructed to bend from the straight or non-use or open configuration illustrated in Figures 2 and/or 4 to the bent or "scissored" or closed configuration of Figure 3. In the Figure 3 configuration, everting platforms 130, 140 are disposed generally parallel to each other on the same side of penetrating element 170, e.g. the underside as viewed in Figure 3. Additionally, everting platforms 130, 140 are apposed, as are spacing elements 150, 160.

As illustrated in Figure 3, spacing elements 150, 160 and penetrating element 170 generally define elevation line 180. Everting platforms 130, 140 generally define elevation line 190. Lines 180, 190 define distances from bend 120 that can be considered inner and outer radii, respectively. Because line 180 is closer to bend 120, line 180 can be considered to define an inner radius of staple 100. Similarly, line 190 can be considered to define an outer radius of staple 100. Additionally, Figure 3 illustrates side-by-side offset axes 200, 210 of staple 100. Axes 200, 210 are offset from each other in two dimensions, e.g. a first dimension as viewed in the direction of lines 180, 190, and a second dimension as viewed in the direction of everting platforms 130, 140, in Figure 3. In its closed configuration, staple 100 is bent in a "U" shape to form two legs 220, 230 separated by bend 120. Legs 220, 230 are disposed along axes 200, 210 and thus are offset from each other in two dimensions.

Figures 5-7 show staple 100 in use. As shown, staple 100 joins inner layer (intima) 240 of anatomical structure 250 to inner layer (intima) 260 of anatomical structure 270. Staple 100 keeps lumen 280 between anatomical structures 250, 270 free of exposure to cut tissue edges 290, ends 300, 310 of anatomical structures 250, 270, and all portions of staple 100 itself, including penetrating element 170. Lumen 280 is also free of suture and other foreign bodies. Thus, staple 100 causes immediate and long-term improvements in the patency of the anastomosis by reducing the likelihood of clot formation, scarring, stenosis and other complications.

When staple 100 is in its closed configuration around cut ends 300, 310 of anatomical structures 250, 270, spacing elements 150, 160 are in an apposed relationship and cut ends 300, 310 are held together between spacing elements 150, 160. Additionally, everting platforms 130, 140 are in an apposed relationship, with cut ends 300, 310 held together between everting platforms 130, 140. Penetrating element 170 penetrates ends 300, 310. The distance between apposed spacing elements 150, 160 is less than the distance between apposed everting platforms 130, 140, as shown. As shown in e.g. Figure 6, apposed spacing elements 150, 160 and/or penetrating element 170 define inner radius 180 of closed staple 100, and apposed everting platforms 130, 140 define outer radius 190 of closed staple 100, radii 180, 190 being considered to originate at bend 120 in staple 100. Because penetrating element 170 is on the different, inner radius 180, it is generally assured that penetrating element 170 is excluded from lumen 280.

As shown in Figures 8-9, everting platform 140 moves laterally or transversely with respect to staple body 110 as staple 100 is closed, such that the direction of closure 320 is at an angle to staple body 110. A method of bending a surgical staple according to an embodiment of

the invention includes moving everting platform 140, disposed at one end of staple 100, to be parallel to and adjacent to everting platform 130 disposed at an opposite end of staple 100. Spacing element 160 disposed at one end of staple 100 becomes apposed to spacing element 150 disposed at the opposite end of staple 100. Spacing elements 150, 160 are disposed adjacent to and generally parallel to penetrating element 170. Everting platform 140 moves in direction of closure 320 to its disposition parallel to and adjacent to everting platform 130. Direction of closure 320 is disposed at an angle, e.g. about 15° to about 20°, to longitudinal axis 145 extending between everting platforms 130, 140. Thus, everting platforms 130, 140 are moved from an offset configuration, illustrated in Figure 8, in which platforms 130, 140 are offset from each other along their respective longitudinal axes, to a non-offset configuration, illustrated in e.g. Figure 3, in which everting platforms 130, 140 are aligned with each other.

Turning to Figures 10-15, staple devices according to embodiments of the invention include two main parts. The first part is staple 400, defining a generally curved shape and supporting a fixed eversion platform 410 securely and immovably affixed thereto, according to one embodiment. Staple 400 can be a free-standing staple, or attached to a suture or other delivery system, for example. The second part is free eversion platform 420, which is supportable by staple 400 and slidable relative thereto in a "threaded" relationship.

Both staple 400 and free eversion platform 420 preferably have a substantially "D" - shaped cross section 430, to predictably orient eversion platform 420. Of course, other cross-sectional shapes of the staple and free eversion platform are contemplated, according to embodiments of the invention. Staple 400 and platform 420 preferably are made of a biocompatible material. At least the staple is malleable, according to a preferred embodiment, so

that it can be crimped into a closed position with a closing or crimping device. According to other embodiments, described below, a memory metal eliminates or reduces the need for a separate closing device.

Free eversion platform 430 generally comprises two parts: collar or spacing element 440 and eversion body or platform 450. Eversion platform 450 preferably is made of a biocompatible material similar to staple 400. However, it is substantially non-deformable, according to this embodiment. Collar 440 slightly overhangs eversion platform 420 in the axis of staple 460, as indicated at 460 in Figure 11. Overhang 460 substantially prevents apposing eversion platforms 410, 420 from crushing cut ends 470, 480 of vascular or other structures 490, 500 in the anastomosis, by keeping them slightly separated from one another in the closed position. Thus, any tissue in the anastomosis is approximated without being strangulated. Additionally, lumen 510 is kept free of exposure to cut tissue edges 520, 530, staple 400, eversion platforms 410, 420, suture, or other structures that might threaten the patency of the anastomosis.

According to embodiments of the invention, either eversion platform 410, 420 illustrated in e.g. Figure 10 can be fixed or free, or both can be free. Everting staple 400 likely is easier to deploy, however, if one platform is fixed and the other is free, as illustrated. Structurally, platforms 410, 420 are generally identical according to one embodiment.

According to the illustrated embodiment, fixed eversion platform 410 is nearer trailing end 535 of staple 400, especially when it is to be deployed via a suture or other delivery mechanism. Suture can be attached to the leading end 537 of the staple, for example, and free eversion platform 420 deployed after engaging and penetrating the two vascular or other

structures 490, 500 with staple 400. The body of staple 400, or a portion thereof, thus is a penetrating element. According to one embodiment, free eversion platform 420 is threaded over a needle and suture, is advanced along the suture to staple 400, and then is advanced to a desired position along staple 400 as shown in e.g. Figure 12. A closing/crimping device or other means then brings the paired eversion platforms 410, 420 into final juxtaposition to each other as staple 400 is closed, in the manner of e.g. Figure 13. Eversion platforms 410, 420 are the fulcrum for closing staple 400.

Of course, two separate free eversion platforms 410 can be employed, with neither affixed to staple 400 at least until after staple 400 engages the two vascular structures 490, 500. The free eversion platforms slide over suture and/or the respective ends of staple 400, while staple 400 is still in an open position. According to this embodiment, and/or according to those described earlier, suture can be attached to either or both ends of staple 400.

As shown in Figure 14, collars 440 and eversion bodies 450 of eversion platforms 410, 420 define inner radius 540 and outer radius 550, respectively, of staple 400. Figure 15 shows multiple closed staples 400 disposed in a radial plane, with eversion bodies 450 disposed in the anastomotic plane, in an end-to-side anastomosis.

According to embodiments of the invention, a plurality of everting staples can be employed to create a single anastomosis, as shown in Figure 15, by themselves or optionally in combination with supplemental adhesives, suture, etc. to reduce the number of staples needed. Of course, each eversion platform and staple can be appropriately dimensioned to suit a particular patient, surgical procedure, surgical environment or other factor. Device pairs or combinations of different types or sizes can be used in the same anastomosis, if desired.

As referenced earlier, staple devices according to the multiple embodiments of the invention can be free-standing staples and/or can be connected to a delivery system for the staple device. For example, a flexible element such as suture, suture wire, wire or equivalent (not shown) can extend from a separation point at or near the penetrating element and terminate at a needle (not shown). Staple devices according to embodiments of the invention preferably are made of a biocompatible material, e.g. titanium, stainless steel, nitinol, etc. Such staple devices preferably are malleable, for crimping into a closed position with a closing or crimping device, and/or are constructed of a memory material or other material that can be induced to deform into a desired configuration, e.g. a closed configuration. In the case of a memory material such as nitinol, the staple device can be formed in the closed position, sprung open and delivered to the tissues, and then released from an e.g. delivery system after springing back into a closed position. Such memory material eliminates the need for complicated crimping tools, which are complex and potentially damaging to delicate tissues during deployment due to their bulk and the ergonomics required to deploy them.

Spacing elements according to embodiments of the invention substantially prevent the apposing everting platforms from crushing the cut ends of the vascular or other structures in the anastomosis, by keeping the everting platforms slightly separated from one another in the closed position of the staple. Thus, any tissue in the anastomosis is approximated without being strangulated, consistent with the surgical adage: "approximate, don't strangulate." If the eversion platforms were not kept slightly apart in the closed position, the tissue engaged between them could be crushed to death (necrose) closer to the lumen. With particular reference to e.g. Figures 5-7, but also with reference to other embodiments, tissue is engaged in the closed staple

with more tissue compression at the spacing elements and less tissue compression at the offset everting platforms. Tissue engagement and compression in this manner accomplishes approximation without strangulation, ensuring viability of the tissue at the most critical point of the anastomosis, namely, the juncture of the two structures being anastomosed.

As referenced above, a plurality of the everting staple devices described herein can be used in a single anastomosis, or a single device can be used. In the case of a single device, one or more sutures, one or more conventional or other type of staples, one or more areas of biological adhesive and/or other means additionally can be used, e.g. at least directly opposite one or each staple device described herein, to complete the anastomosis. In the case of multiple staple devices, whatever the type, it is desirable to space each device at selected points around the circumference of the anastomosis, e.g. at quadrant points (e.g. 12 o'clock, 3 o'clock, 6 o'clock and 9 o'clock positions) or half points (e.g. 12 o'clock and 6 o'clock positions).

Non-everting staple devices can be used at e.g. the heel and toe of an anastomosis formed using a longitudinal (i.e. in the direction of blood flow) opening in the artery or other recipient vessel, and everting staple devices can be used along the sides of the anastomosis between the heel and toe. Such use of non-everting staple devices would reduce the possibility of compromising the circumference of the recipient vessel at the heel and toe. Use of adhesive, suture, or other connection devices or methods in addition to or instead of everting staples can also reduce possible complications and/or the number of everting staple devices needed to form an anastomosis. Staple devices all of the everting type can be used more readily with a transverse (i.e. in the direction perpendicular to blood flow) opening in the recipient vessel.

Of course, each staple can be appropriately dimensioned to suit a particular patient, surgical procedure, surgical environment or other factor. Devices of different sizes can be used in the same anastomosis, if desired.

In use, according to one embodiment, the surgeon or other medical professional penetrates the walls of the vascular or other anatomical structures using one or more needles attached to e.g. suture or other material. The suture, in turn, is attached at or near e.g. a penetrating element of the staple device or to another suitable point at, on, or in association with the staple device. According to alternative embodiments, the staple is a free-standing staple and/or includes delivery mechanisms other than suture and one or more needles.

While the invention has been described with respect to specific embodiments, the invention should not be considered limited to the specific embodiments illustrated and described herein. For example, embodiments of the invention apply not only to anastomoses of vascular structures in e.g. minimally invasive thoracic surgical situations, but also to conventional surgical techniques and to anatomical structures other than vascular structures. Embodiments of the invention apply to anastomosing prosthetic tubular grafts to vascular structures or to each other. Specific features described with respect to one embodiment are also to be considered useable with the other embodiments disclosed and contemplated herein. Other modifications and changes are readily discernible from the specification and will be apparent to those of ordinary skill.